Janssen COVID-19 Vaccine (Johnson & Johnson)

Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older

Note: For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

Assess persons 18 years of age and older for vaccination with Janssen COVID-19 Vaccine based on the following criteria:

- If the recipient has never received a COVID-19 vaccine, administer 1 dose of Janssen COVID-19 vaccine.
- If the recipient has received 1 dose of a Janssen COVID-19 Vaccine, no additional primary-series doses are needed. A booster dose is recommended 2 months (8 weeks) after the primary Janssen dose; any FDA-authorized or approved COVID-19 vaccine may be given.
- If the recipient has received 1 dose of an mRNA vaccine, the same brand should be administered for the second dose of the primary series.
- If 2 doses of an mRNA vaccine or a single dose of Janssen COVID-19 Vaccine has been administered, the person is considered fully vaccinated 2 weeks after completing the primary vaccination series.
- In situations where the first dose of an mRNA COVID-19 vaccine was received but the patient is unable to complete the series with either the same or different mRNA COVID-19 vaccine, (e.g., due to contraindication) consideration may be given to vaccination with the Janssen COVID-19 Vaccine at a minimum interval of 28 days after receipt of mRNA COVID-19 vaccine dose. However, vaccination should be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions. Consider referral to an allergist-immunologist.*
- Thrombocytopenia syndrome (TTS) and thrombocytopenia:
  - Inform women aged 18-49 years of the increased risk of thrombosis with thrombocytopenia syndrome (TTS) in their age group after Janssen COVID-19 vaccination and about the availability of other authorized vaccines (i.e., mRNA vaccines).
  - A second dose of Janssen COVID-19 vaccine is not recommended for people who had TTS after their first dose. These people may receive a dose of mRNA COVID-19 vaccine as a booster dose at least 2 months (8 weeks) after their dose of Janssen vaccine and after their clinical condition has stabilized.
    - » A consultation with the patient's clinical team, including hematologists or other specialists, should be considered.
  - Offer another FDA-authorized or approved vaccine (i.e., mRNA vaccine) to unvaccinated persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia (e.g., heparin-induced thrombocytopenia) if it has been 90 days or less since their illness resolved. After 90 days, patients may be vaccinated with any FDA-authorized or approved COVID-19 vaccine.

NOTE: Persons at risk or with a history of other thrombosis not associated with thrombocytopenia can receive an FDA-authorized or approved vaccine

- People with a history of Guillain-Barré Syndrome (GBS):
  - Can receive any FDA-authorized or approved COVID-19 vaccine. However, given the possible association between the Janssen COVID-19 Vaccine and an increased risk of GBS, discuss with these patients the availability of mRNA COVID-19 vaccines that offer protection against COVID-19.
- Persons who have received HCT or CAR-T-cell therapy
  - Revaccinate persons who received doses of COVID-19 vaccine prior to receiving HCT or CAR-T-cell therapy with a primary series at least 3 months (12 weeks) after transplant or CAR-T-cell therapy.
- Booster doses:
  - Administer a booster dose at least 2 months (8 weeks after completion of the Janssen COVID-19 Vaccine primary dose to:
    - » All persons who received the Janssen COVID-19 Vaccine, including those moderately and severely immunocompromised
    - » Use of heterologous booster doses is allowed. Any FDA-approved or FDA-authorized COVID-19 vaccine product can be administered.
- Additional Clinical Considerations
  - For people who received a COVID-19 vaccine that is not currently authorized in the United States, guidance can be found at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#people-vaccinated-outside-us

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- Janssen COVID-19 Vaccine may be coadministered with other vaccines without regard to timing, including simultaneous administration.
- For recommendations for COVID-19 vaccination and SARS-CoV-2 infection, see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination

- **Screen for contraindications and precautions.**
  - **Contraindications**
    - History of a:
      - Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
      - Known diagnosed allergy to a component of the vaccine (see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-C for a list of vaccine components)
  - **Precautions**
    - Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
    - Immediate allergic reaction‡ to any non-COVID-19 vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])
      - This includes non-COVID-19 vaccines and therapies with multiple components and the component(s) that elicited the reaction is unknown.
    - Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
    - Contradiction to one type of COVID-19 vaccines (mRNA) is a precaution to other types of COVID-19 vaccines (Janssen)
    - Moderate to severe acute illness

*Consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax Project (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html). Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

·People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose should wait at least 28 days to receive Janssen COVID-19 Vaccine.

· People with a contraindication to Janssen COVID-19 Vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

†Prior to booster vaccination, a conversation between the patient and their clinical team, including hematologists or other specialists, may assist with decisions about using an mRNA COVID-19 vaccine as a booster and the timing of the booster vaccination.

‡For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms, such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site‡
Female or male fewer than 130 lbs	22–25	5/8§ –1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs	22–25	1–1½"	Deltoid muscle of arm
Male 152–260 lbs	22–25	1–1½"	Deltoid muscle of arm
Female 200+ lbs	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs	22–25	1½"	Deltoid muscle of arm

‡Alternately, the anterolateral thigh can be used. A 1.5-inch needle may be used if administering vaccine in this site.

§Some experts recommend a 5/8-inch needle for men and women who weigh less than 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine. Choose the correct needle gauge, needle length, and injection site for persons:
  - 18 years of age:
    - Needle gauge/length: 22-25 gauge, 1-inch
    - Site: Deltoid muscle of arm.
  - 19 years of age and older: See chart on page 2.
  - Follow the manufacturer's guidance for storing/handling punctured vaccine vials.
  - Administer 0.5 mL Janssen COVID-19 Vaccine by intramuscular (IM) injection.
- Document vaccination.
  - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
  - Document each recipient's vaccine administration information:

- Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
- Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
- Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.

- Additional preparation and administration information is available on the manufacturer's website at www.janssencovid19vaccine.com.
- Be prepared to manage medical emergencies.
  - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
    - **30 minutes:** Persons with a history of:
      - A contraindication to another type of COVID-19 vaccine product.
      - Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine.
      - Immediate allergic reaction of any severity to a non-COVID-19 vaccine or injectable therapies
      - Anaphylaxis due to any cause.
      - History of a non-severe, immediate allergic reaction after a previous dose of COVID-19 vaccine
    - **15 minutes:** All other persons
  - Syncope may occur in association with injectable vaccines, in particular among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions.
  - Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.
  - Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.
  - For more information, please see:
    - **Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html**
    - **CDC's *General Best Practice Guidelines for Immunization*, "Preventing and Managing Adverse Reactions," at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html**
    - **Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at https://www.immunize.org/catg.d/p3082.pdf**

- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
  - While this vaccine is under Emergency Use Authorization (EUA), healthcare professionals are required to report to VAERS:
    - Vaccine administration errors (whether associated with an adverse event [AE] or not)
    - Serious AEs (irrespective of attribution to vaccination)
    - Multisystem inflammatory syndrome (MIS) in adults or children
    - Cases of COVID-19 that result in hospitalization or death
    - Any additional AEs and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA
  - Healthcare professionals are encouraged to report to VAERS:
    - Clinically important adverse events that occur after vaccination, even if they are not sure whether the vaccine caused the adverse event

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the Kansas Local Health Departments effective 11/19/2021 until rescinded or until 11/19/2022.

Medical director (or other authorized practitioner)

_____, MD / Ximena Garcia / 11/19/21

Adapted with appreciation from the Immunization Action Coalition (IAC) standing orders

Ashley D. Gum
Acting Secretary